4164-01-P

### DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-N-1305]

Multicriteria-Based Ranking Model for Risk Management of Animal Drug Residues in Milk and

Milk Products; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA or we) is extending the comment period for the risk assessment entitled "Multicriteria-Based Ranking Model for Risk Management of Animal Drug Residues in Milk and Milk Products." A notice of the availability of the risk assessment and our request for comments appeared in the Federal Register of April 30, 2015. We initially established July 29, 2015, as the deadline for the submission of requested comments that can help improve the ranking model approach, including the specific criteria, scoring, and weighting scheme; the scientific data and assumptions used to inform scoring used in the model; the selection of animal drugs evaluated; and the clarity and the transparency of the risk assessment. We are taking this action in response to a request for an extension to allow interested persons additional time to submit comments.

DATES: FDA is extending the comment period on the risk assessment whose availability we announced in a notice published on April 30, 2015 (80 FR 24260). Submit either electronic or written comments on the risk assessment by October 27, 2015.

ADDRESSES: You may submit comments by any of the following methods:

# **Electronic Submissions**

Submit electronic comments in the following way:

• Federal eRulemaking Portal: <a href="http://www.regulations.gov">http://www.regulations.gov</a>. Follow the instructions for submitting comments.

## Written Submissions

Submit written submissions in the following ways:

 Mail/Hand delivery/Courier (for paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

<u>Instructions</u>: All submissions received must include the Docket No. FDA-2015-N-1305. All comments received may be posted without change to <a href="http://www.regulations.gov">http://www.regulations.gov</a>, including any personal information provided. For additional information on submitting comments, see the "Comments" heading of the SUPPLEMENTARY INFORMATION section of this document.

<u>Docket</u>: For access to the docket to read background documents or comments received, go to <a href="http://www.regulations.gov">http://www.regulations.gov</a> and insert the docket number(s), found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Jane Van Doren, Center for Food Safety and Applied Nutrition (HFS-005), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-2927.

#### SUPPLEMENTARY INFORMATION:

# I. Background

In the <u>Federal Register</u> of April 30, 2015, FDA published a notice announcing the availability of a risk assessment entitled "Multicriteria-Based Ranking Model for Risk Management of Animal Drug Residues in Milk and Milk Products," with a 90-day comment period to request comments on the risk assessment.

We received a request for a 90-day extension of the comment period for the risk assessment. The request conveyed concern that the current 90-day comment period does not allow sufficient time to develop meaningful or thoughtful comments to the risk assessment.

FDA has considered the request and is extending the comment period for the risk assessment for 90 days, until October 27, 2015. We believe that a 90-day extension allows adequate time for interested persons to submit comments.

## II. Request for Comments

Interested persons may submit either electronic comments regarding this document to <a href="http://www.regulations.gov">http://www.regulations.gov</a> or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <a href="http://www.regulations.gov">http://www.regulations.gov</a>.

### III. Electronic Access

Persons with access to the Internet may obtain the risk assessment at <a href="http://www.fda.gov/Food/FoodScienceResearch/RiskSafetyAssessment/ucm443549.htm">http://www.fda.gov/Food/FoodScienceResearch/RiskSafetyAssessment/ucm443549.htm</a>.

Dated:	July	24,	2015.
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Leslie Kux,

Associate Commissioner for Policy.

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